FLORIDA DEPARTMENT OF HEALTH

Jeb Bush
Governor

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Secretary

April 20, 1999 '99 APR 27 P1:43

Documents Management Branch
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

To Whom It May Concern:

This is in reply to your Request for Comments published in the Federal Register, January 21, 1999, No. 13. The Office of Disease Control, Bureau of Epidemiology for the Florida Department of Health responds as follows:

Performance Standards for *Vibrio vulnificus*: Request for Comments [Docket No. 98P-0504].

BACKGROUND

Florida was the first state to require reporting of *Vibrio* infections other than infection with *V. cholerae* O1 and has seen the largest number of reported cases. *Vibrio vulnificus* infections from raw oyster consumption have received the greatest attention probably because of their high mortality. In a 1997 publication by W.G. Hlady describing *Vibrio* infections associated with raw oyster consumption in Florida between 1981 and 1994, it was found that a 54% case-fatality rate was observed among patients with primary septicemia due to *V. vulnificus* infection.

In 1992 Florida adopted an administrative code which specified that all food service establishments serving raw oysters display a warning notice concerning risk associated with consuming raw oysters. Such a notice is also required on all wholesale shellstock and shucked product.

REQUEST FOR INFORMATION AND REVIEWS

1. AmeriPure Technology: we are not familiar enough with this technology to comment as to whether it could be readily employable by the shellfish industry, or to address what barriers may exist other than one of possible product palatability. This would be an area best addressed by the Department of Environmental Protection, which has regulatory authority over the shellfish industry.

2. Other Technologies: Again, this is possibly best addressed by another industry. We are aware of technologies (such as pasteurization) that reduce the numbers of *V. vulnificus*, but none that can assure retaining the flavor and palatability of raw oysters. There are processes such as freezing and pressure application, but these may also render an unpalatable product. Irradiation may be the best consideration, but acceptability by consumers requires more effort.

98P-0504

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3. Reliability of Technologies: Not able to answer. However, we would support implementation of a technology in which USFDA had confidence would eliminate *V. vulnificus* in epidemiologically implicated areas. Any mandated process would have associated regulatory compliance concerns and costs.

4. Nondetectable Level: Without a known infective dose the question regarding setting of a performance standard is difficult to answer. To set a standard based on months when this organism is at low levels does not seem in the best interest of public health. February may no longer hold as a month in which illness has not been reported as Florida received a report of a *V. vulnificus* gastroenteritis case (associated with consumption of raw oysters) in February 1999.

5. Performance Standard: Whether or not a performance standard should apply to other molluscan shellfish would depend upon epidemiological data linking illness to them.

6. Performance Standard Costs: Quantifiable costs associated with implementation of any process to meet a performance standard would obviously exist and would depend heavily upon the process itself. The consumer would most likely bare the bulk of the cost. However, the cost of non-treatment continues to be medical costs associated with the cases and deaths due to *V. vulnificus* infections. Without specific knowledge of the proposed technology and industry costs in general, we are unable to comment further.

7. Performance Standard Benefits: Reduced illness would be one major benefit experienced by the population at risk. Consumer confidence may increase due to belief that the result is a safer product. Industry not affected by the standard, if applied for only those areas epidemiologically implicated, would possibly have some market advantage.

8. Vibrio parahemolyticus Standard: It is recommended that a risk assessment be undertaken before a non-detectable standard is considered for this pathogen and risk management techniques are implemented. Other methods traditionally used, such as closing harvest areas during an outbreak, should be implemented in the meantime.

CONCLUSION

The Bureau of Epidemiology cannot endorse the petition at this time without needed supporting documentation that would include, at least, comprehensive epidemiologic data, risk assessment, and cost/benefit information.

If you need further assistance, please contact Linda Baldy, at (850) 488-2905.

Sincerely,

William J. Bigler

for Richard S. Hopkins, M.D., M.S.P.H.
State Epidemiologist

RSH/lb
cc: Landis K. Crockett, M.D., M.P.H., Division Director for Disease Control
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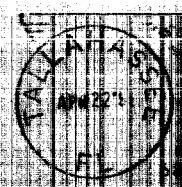

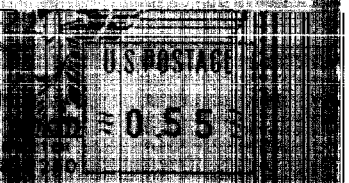

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